

REMARKS/ARGUMENTS

The Pending Claims

Claims 1-4 and 6-11 are pending and are directed to a method of growing spermatogonial stem cells.

The Amendments to the Claims

Claim 1 has been amended to recite that the stem cells are mammalian spermatogonial stem cells, as supported by claim 5 (now canceled) and the specification at, for example, page 20, lines 20-29. Additionally, claim 1 has been amended to recite that the stem cells are cultured in (a) GDNF, neurturin, or artemin and (b) LIF, as supported by the specification at, for example, page 13, lines 22-34. No new matter has been added by way of these amendments.

Summary of the Office Action

The Office has rejected claims 1-11 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

Reconsideration of this rejection is hereby requested.

Discussion of the Enablement Rejection

The Office contends that the inventive methods are not enabled by the specification. This rejection is traversed for the following reasons.

A. Mammalian Spermatogonial Stem Cells

The Office contends that the specification does not provide guidance for growing spermatogonial stem cells other than mammalian spermatogonial stem cells. In an effort to advance prosecution, the claims have been amended to recite that the stem cells are mammalian spermatogonial stem cells.

B. GDNF or an Equivalent Thereto

The Office contends that the specification is not enabling for the use of all of the compounds encompassed by GDNF equivalents or GDNF-like compounds. The pending claims, as amended, recite that the medium contains GDNF, neurturin, or artemin.

The relationship between GDNF family ligands (GDNF, neurturin, artemin, and the like) and their receptors was clearly elucidated at the molecular level at the time the application was filed (see, e.g., Airaksinen et al., *Nature Reviews*, 3: 383-394 (2002); copy enclosed). In particular, the crosstalk of neurturin and artemin with the GDNF receptor and of GDNF with the neurturin and artemin receptors was well-known in the art (see, e.g., page 384, paragraph bridging columns 1 and 2). As such one of ordinary skill in the art would recognize based on the teaching in the specification and what was known in the art at the time of filing the application that the culturing medium for use in the inventive methods could include GDNF or equivalents thereto, such as neurturin and artemin. Additionally, Example 3 of the specification demonstrates that the use of neurturin in place of GDNF in the medium results in the growth of cultured stem cells.

C. Growth Medium Comprising GDNF and LIF

The Office contends that that the specification is not enabling for methods using a medium containing only GDNF and LIF without any growth factors or serum. As described in the accompanying Declaration under 37 C.F.R. § 1.132 of Takashi Shinohara, the addition of growth factors, such as EGF and bFGF, is not necessary to achieve the growth of the spermatogonial stem cells. In particular, the experiments set forth in the Rule 132 declaration demonstrate that spermatogonial stem cells can grow in a medium containing GDNF and LIF without any other growth factors at a level similar to that achieved using a medium containing GDNF, LIF, EGF, and bFGF (see page 4, first and last paragraphs, of the Rule 132 declaration).

At the time the application was filed, it was well-known in the art that serum (e.g., fetal calf serum) could be used for culturing various mammalian cells. Therefore, it would be well within the ability of the ordinarily skilled artisan to add serum to the medium in the inventive methods based on the specification and conventional teachings.

In view of the foregoing, Applicants believe that the specification is enabling for the inventive methods and request that the enablement rejection be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: March 5, 2009